

REMARKS/ARGUMENTS**Claims**Double Patenting (Provisional) Rejection of Claims 1 – 14

The Office Action provisionally rejected Claims 1 - 14 under the judicially created doctrine of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 - 6 of copending Application No. 10/581,576.

Applicants request this Provisional Rejection of nonstatutory obviousness-type double patenting be held in abeyance until the claims of copending Application No. 10/581,576 are examined and are in condition for allowance. It is unclear at this stage in the examination process of either application whether any claims in these applications will qualify for a rejection of nonstatutory obviousness-type double patenting at the time of allowance.

Additionally, Applications 10/581,576 and 10/581,576 were filed on the same day at the USPTO and have the same Priority dates from the foreign applications.

The Examiner is requested to hold in abeyance the Double Patenting Rejection. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1 - 14.

35 USC § 112 ¶ 1 Rejections of Claims 1 - 14

The Office Action rejected Claims 1 - 14 under 35 USC § 112 ¶ 1 as failing to comply with the written description requirement.

**Claims 2 and 12**

The Office Action states “obesity and adipogenesis-involved diseases cannot be prevented.”

Applicants have amended Claims 2 and 12 to remove the words “prevent” and “prevention”.

The Examiner is requested to remove the 35 USC § 112 ¶ 1 Rejection of Claims 2 - 12. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2 and 12.

Claims 1, 2, and 5 – 12

The Office Action states the “specification does not provide adequate written description of any species of Cucurbitaceae family” and “applicant is in possession [of] a purified extract isolated from pumpkin, water-melon, sponge gourd, gourd, and cucumber as indicated in claims 3 and 4.”

Applicants have amended Independent Claims 1 and 12 to incorporate the features in Claim 3 acknowledged by the Examiner as providing adequate Written Description, and Canceled Claim 2.

The Examiner is requested to remove the 35 USC § 112 ¶ 1 Rejection of Claims 1, 2, and 5 – 12. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1, 2, and 5 – 12.

35 USC § 112 ¶ 2 Rejections of Claims 1 - 14

The Office Action rejected Claims 1 - 14 under 35 USC § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1

The Office Action states” Claim 1 recites ‘subjecting said chloroform-soluble fraction to silica gel column chromatography with a solvent mixture of hexane: chloroform: methanol (16:15:1) to obtain 11 sub-fractions, subjecting 9<sup>th</sup> fraction...’, without knowing the flow rate and amount of solvent being used, the claim fails to point out how to collect the 11 sub-fractions, and thus the 9<sup>th</sup> sub-fractions is indefinite.”

Applicants disagree with the conclusion that Claim 1 is indefinite for not reciting a flow rate and amount of solvent, and Traverse.

A claim does not have to recite each and every step in a process if the omitted steps are common knowledge to a person skilled in the art. The parameters of silica gel column chromatography (e.g., flow rate; solvent mixture; column diameter and length; bead size, composition and manufacturer) are routinely determined for each experiment or isolation procedure. A skilled person in the art can easily obtain the 11 sub-fractions based on the teachings of the subject specification and technical knowledge generally established in the art.

The Specification gives examples of the parameters selected for a silica gel column chromatography to isolate the disclosed compound. See for example: Page 9, paragraph 2; and Page 16, “Example 6. Preparation of purified cmc-9 extract”.

Additionally, the flow rate and the amount of solvent used as an eluent is conventionally determined depending on the amount of a resin filled in a column according to the amount of a sample to be loaded, as disclosed in *Microscale organic laboratory with multistep and multiscale syntheses*, Dana W. Mayo, Ronald M. Pike, Peter K. Trumper, 3<sup>rd</sup> edition, John Wiley & Sons.

Further, it is obvious that several fractions can be separated in a TLC pattern by a conventional silica gel chromatography as disclosed in the Examples of the subject specification, and then the fraction showing most potent anti-adipogenic and anti-obesity activity (i.e., 9<sup>th</sup> fraction) can be selected among the separated fractions through *in vitro* bioassay (i.e., adipocyte differentiation).

The Examiner is requested to remove the 35 USC § 112 ¶ 2 Rejection of Claims 1 - 14. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1 - 14.

#### 35 USC § 101 Rejection of Claims 2 – 13

The Office Action rejected Claims 2 - 13 under 35 USC 101 because the claimed invention is not supported by either an asserted utility or a well established utility. The Office Action states “The claims recite ‘prevention of obesity and adipogenesis-involved diseases’. The broadest reasonable interpretation of the term obesity and adipogenesis-involved diseases merely require that one subject gets obese. There is no evidence that obesity and adipogenesis-involved diseases would be prevented, therefore the utility would not be credible.”

In an attempt to progress prosecution and without agreeing that the “claimed invention is not supported by either an asserted utility” does not satisfy the 35 USC § 101 requirement, the applicants have amended Claim 2 to add the feature “to obtain a beneficial result selected from the group consisting of inhibition of accumulation of adipocytes, inhibition of accumulation of triglycerides, reduction of body weight, treatment of obesity and treatment of adipogenesis-involved diseases”. Support for this amendment can be found through out the specification; for example: Industrial Applicability on page 31.

The Examiner is requested to remove the 35 USC 101 Rejection of Claims 2 - 13. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 2 - 13.

#### 35 USC § 103(a) Rejection of Claims 1 - 14

The Office Action rejected Claims 1 – 14 under 35 USC § 103(a) as being unpatentable over JP 59203451, in view Tang et al (Zhongcaoyao 32(9), 773-775, 2001).

The Office Action stated “JP 59203451 teaches saponins (inherently water soluble) isolated from aerial parts of *Luffa cylindrical* (Curcubitaceae family) are health food additives that are effective in controlling obesity. JP 59203451 does not teach the detailed isolation procedure as claimed. Tang et al teach that a crude extract of root of *Luffa cylindrical* was prepared by decocting with boiling water, chromatographed on microporous resin column, and eluted by 60% ethanol. The eluent was separated on silica gel column by eluting with chloroform, and various proportions of chloroform-acetone, and chloroform-methanol. Eleven compounds were isolated and identified as triterpenoid saponins”

The applicant disagrees with the conclusion in the Office Action that Claims 1 – 14 are unpatentable over JP 59203451, in view Tang (2001), and Traverse.

A Declaration is submitted from Yoon Ah Lee to present evidence showing that the disclosed process in Claim 1 does not obtain the saponins of JP59203451.

The Examiner is requested to remove the 35 USC 103(a) Rejection of Claims 1 - 14. In light of the foregoing arguments and amendments to the claims, the Examiner is respectfully requested to allow Claims 1 - 14.

#### No Disclaimers or Disavowals

Although the present communication may include alterations to the claims, the Applicants are not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related

prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

#### Conclusion

Claims 1, 2, and 4 - 14 are Pending. Claims 1, 2 and 12 are Currently amended. Claim 3 is Canceled. No New Matter was entered with these amendments. Applicants respectfully request the entrance of the amendments.

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claim set are presented above. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested and it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

No additional fees are believed due; however, the Commissioner is authorized to charge any additional fees now and in the future which may be due, including any fees for additional extension of time, or credit overpayment to credit card information.

Date: March 20, 2008

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